

## **AMENDMENTS TO THE CLAIMS**

1. (Original) A method for producing an orally administrable edible agent of laminate film form characterized by comprising:

an orally administrable agent layer forming step for forming an orally administrable edible agent layer having a predetermined thickness on a surface of a resin film by coating and drying;

an orally administrable agent layer pressure bonding step for joining together two orally administrable agent layer- formed resin films provided with orally administrable edible agent layers of the same ingredient or different ingredients obtained in said orally administrable agent layer forming step so that orally administrable edible agent layer surfaces face each other, and pressurizing the resin films at back surfaces by a pair of press rolls to bond the orally administrable edible agent layers together; and

a resin film delaminating step for delaminating only one of said joined two resin films by conveying the two resin films sandwiching said bonded orally administrable edible agent layers in a direction substantially conforming to a tangential direction at a pressurization zone of said pair of press rolls, and drawing only one of said two resin films sandwiching the bonded orally administrable edible agent layers in a direction different from said conveying direction along a peripheral surface of a delamination roll disposed in the conveying direction while continuously conveying the other resin film retaining the orally administrable edible agent layers in said conveying direction.

2. (Original) A method for producing an orally administrable edible agent of laminate film form characterized by comprising:

an orally administrable agent layer forming step for forming an orally administrable edible agent layer having a predetermined thickness on a surface of a resin film by coating and drying;

an orally administrable agent layer pressure bonding step for joining together two orally administrable agent layer- formed resin films provided with orally administrable edible agent layers of the same ingredient or different ingredients obtained in said orally administrable agent

layer forming step so that orally administrable edible agent layer surfaces face each other, and pressurizing the resin films at back surfaces by a pair of press rolls to bond the orally administrable edible agent layers together;

a resin film delaminating step for delaminating only one of said joined two resin films by conveying the two resin films sandwiching said bonded orally administrable edible agent layers in a direction substantially conforming to a tangential direction at a pressurization zone of said pair of press rolls, and drawing only one of said two resin films sandwiching the bonded orally administrable edible agent layers in a direction different from said conveying direction along a peripheral surface of a delamination roll disposed in the conveying direction while continuously conveying the other resin film retaining the orally administrable edible agent layers in said conveying direction;

a multiple orally administrable agent layers pressure bonding step for joining together the resin film retaining the bonded plural orally administrable edible agent layers obtained in said resin film delaminating step and another resin film provided with a single or a plurality of orally administrable edible agent layer/layers of the same or different ingredient as or from said bonded plural orally administrable edible agent layers so that orally administrable edible agent layer surfaces face each other, and pressurizing the resin films at back surfaces by a pair of press rolls to bond the orally administrable edible agent layers together; and

a resin film delaminating and removing step for delaminating only one of said joined two resin films by conveying the two resin films sandwiching said bonded multiple orally administrable edible agent layers in a direction substantially conforming to a tangential direction at a pressurization zone of the pair of press rolls, and drawing only one of said two resin films sandwiching the bonded multiple orally administrable edible agent layers in a direction different from said conveying direction along a peripheral surface of a delamination roll disposed in the conveying direction while continuously conveying the other resin film retaining the multiple orally administrable edible agent layers in said conveying direction.

3. (Original) A method for producing an orally administrable edible agent of laminate film form characterized by comprising:

an orally administrable agent layer forming step for forming an orally administrable edible agent layer having a predetermined thickness on a surface of a resin film by coating and drying;

a rolled film forming step for winding the orally administrable agent layer-formed resin film obtained in said orally administrable agent layer forming step into a roll to form a rolled film;

a rolled film orally administrable agent layer pressure bonding step for unwinding and joining together two rolled films provided with orally administrable edible agent layers of the same ingredient or different ingredients obtained in said rolled film forming step so that orally administrable edible agent layer surfaces face each other, and pressurizing the resin films at back surfaces by a pair of press rolls to bond the orally administrable edible agent layers together; and

a resin film delaminating step for delaminating only one of said joined two resin films by conveying the two resin films sandwiching said bonded orally administrable edible agent layers in a direction substantially conforming to a tangential direction at a pressurization zone of said pair of press rolls, and drawing only one of said two resin films sandwiching the bonded orally administrable edible agent layers in a direction different from said conveying direction along a peripheral surface of a delamination roll disposed in the conveying direction while continuously conveying the other resin film retaining the orally administrable edible agent layers in said conveying direction.

4. (Original) A method for producing an orally administrable edible agent of laminate film form characterized by comprising:

an orally administrable agent layer forming step for forming an orally administrable edible agent layer having a predetermined thickness on a surface of a resin film by coating and drying;

a rolled film forming step for winding the orally administrable agent layer-formed resin film obtained in said orally administrable agent layer forming step into a roll to form a rolled film;

a rolled film orally administrable agent layer pressure bonding step for unwinding and joining together two rolled films provided with orally administrable edible agent layers of the

same ingredient or different ingredients obtained in said rolled film forming step so that orally administrable edible agent layer surfaces face each other, and pressurizing the resin films at back surfaces by a pair of press rolls to bond the orally administrable edible agent layers together;

a resin film delaminating step for delaminating only one of said joined two resin films by conveying the two resin films sandwiching said bonded orally administrable edible agent layers in a direction substantially conforming to a tangential direction at a pressurization zone of said pair of press rolls, and drawing only one of said two resin films sandwiching the bonded orally administrable edible agent layers in a direction different from said conveying direction along a peripheral surface of a delamination roll disposed in the conveying direction while continuously conveying the other resin film retaining the orally administrable edible agent layers in said conveying direction;

a plural orally administrable agent layers-retained rolled film forming step for winding the resin film retaining the bonded plural orally administrable edible agent layers obtained in said resin film delaminating step into a roll to form a rolled film;

a rolled film multiple orally administrable agent layers pressure bonding step for unwinding and joining together the plural orally administrable agent layers-retained rolled film retaining the bonded plural orally administrable edible agent layers obtained in said plural orally administrable agent layers-retained rolled film forming step and another rolled film retaining a single or a plurality of orally administrable edible agent layer/layers of the same or different ingredient as or from the bonded plural orally administrable edible agent layers so that orally administrable edible agent layer surfaces face each other, and pressurizing the resin films at back surfaces by a pair of press rolls to bond the orally administrable edible agent layers together; and

a resin film delaminating and removing step for delaminating only one of said joined two resin films by conveying the two resin films sandwiching said bonded multiple orally administrable edible agent layers in a direction substantially conforming to a tangential direction at a pressurization zone of the pair of press rolls, and drawing only one of said two resin films sandwiching the bonded multiple orally administrable edible agent layers in a direction different from said conveying direction along a peripheral surface of a delamination roll disposed in the conveying direction while continuously conveying the other resin film retaining the multiple orally administrable edible agent layers in said conveying direction.

5. (Currently Amended) The method for producing an orally administrable edible agent of laminate film form according to claim 1~~or~~2, characterized in that one resin film to be delaminated in said resin film delaminating step is previously subjected to release treatment at least on a surface provided with the orally administrable edible agent layers.

6. (Original) The method for producing an orally administrable edible agent of laminate film form according to claim 2, characterized in that one resin film to be delaminated in said one resin film to be delaminated in said resin film delaminating and removing step is previously subjected to release treatment at least on a surface provided with the orally administrable edible agent layers.

7. (Currently Amended) The method for producing an orally administrable edible agent of laminate film form according to claim 3~~or~~4, characterized in that one resin film to be delaminated in said resin film delaminating step is previously subjected to release treatment on both a front surface provided with the orally administrable edible agent layers and an opposite back surface, and the other resin film retaining the orally administrable edible agent layers without being delaminated in said resin film delaminating step is previously subjected to release treatment at least on a back surface provided with no orally administrable edible agent layer.

8. (Original) The method for producing an orally administrable edible agent of laminate film form according to claim 4, characterized in that one resin film to be delaminated in said resin film delaminating and removing step is previously subjected to release treatment on both a front surface provided with the orally administrable edible agent layers and an opposite back surface, and the other resin film retaining the orally administrable edible agent layers without being delaminated in said resin film delaminating and removing step is previously subjected to release treatment at least on a back surface provided with no orally administrable edible agent layer.

9. (Currently Amended) The method for producing an orally administrable edible agent of laminate film form according to ~~any one of claims~~ claim 1 to 4, characterized in that a pressure is

0.05 to 1.5 MPa when the resin films are joined so that said orally administrable edible agent layer surfaces face each other and are pressurized at the back surfaces.

10. (Currently Amended) The method for producing an orally administrable edible agent of laminate film form according to ~~any one of claims claim~~ 1 to 4, characterized in that a temperature of the orally administrable edible agent layer is 50°C to 180°C when the resin films are joined so that said orally administrable edible agent layer surfaces face each other and are pressurized at the back surfaces.

11. (Original) The method for producing an orally administrable edible agent of laminate film form according to claim 10, characterized in that after said orally administrable edible agent layers are bonded and before the resin film is delaminated from the bonded orally administrable edible agent layers, said bonded orally administrable edible agent layers are cooled to a temperature 10°C or more lower than the temperature of the orally administrable edible agent layers when the resin films are joined so that said orally administrable edible agent layer surfaces face each other and are pressurized at the back surfaces, and the temperature of the cooled orally administrable edible agent layers is kept higher than 0°C.

12. (Original) The method for producing an orally administrable edible agent of laminate film form according to claim 10, characterized in that each of said bonded orally administrable edible agent layers contains an edible thermoplastic substance.

13. (Original) The method for producing an orally administrable edible agent of laminate film form according to claim 12, characterized in that said edible thermoplastic substance includes at least one selected from the group consisting of amylose, carboxymethyl cellulose potassium, carboxymethyl cellulose sodium, carboxymethyl cellulose calcium, alkyl ester alginate, sodium alginate, ethylcellulose, eudragit, carboxymethylethylcellulose, carboxymethyl starch, carboxymethyl cellulose, agar, gelatin, shellac, dextran, dextrin, starch, tragacanth, hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose,

hydroxypropylmethylcellulose phthalate, polyvinylpyrrolidone, methacrylic acid copolymer, and methylcellulose phthalate.

14. (Currently Amended) The method for producing an orally administrable edible agent of laminate film form according to ~~any one of claims~~ claim 1 to 4, characterized in that a thickness of each of the orally administrable edible agent layers formed by pressure bonding said orally administrable edible agent layers is 1 to 300  $\mu\text{m}$ .

15. (Currently Amended) The method for producing an orally administrable edible agent of laminate film form according to ~~any one of claims~~ claim 1 to 4, characterized in that said bonded orally administrable edible agent layers are self-supporting laminated films.

16. (Original) The method for producing an orally administrable edible agent of laminate film form according to claim 15, characterized in that the two resin films sandwiching the bonded orally administrable edible agent layers are finally delaminated from the bonded orally administrable edible agent layers.

17. (Original) A pressure bonding apparatus of an orally administrable edible agent of laminate film form characterized by comprising:

a pair of press rolls that draw two resin films each provided with an orally administrable edible agent layer having a predetermined thickness on a surface thereof so that orally administrable edible agent layer surfaces face each other, and pressurize the resin films at back surfaces;

a delamination roll having a diameter of 6 cm or less disposed in a position in a direction substantially conforming to a tangential direction at a pressurization zone of said pair of press rolls in a delivery direction of said pair of press rolls;

a winding shaft that draws and delaminates only one of said two resin films sandwiching the plural orally administrable edible agent layers conveyed from said pair of press rolls to the delamination roll and bonded together, in a direction different from a conveying direction from

said pair of press rolls to said delamination roll, along a peripheral surface of said delamination roll; and

a conveyance mechanism that conveys, when said one resin film is delaminated, the other film retaining the plural orally administrable edible agent layers, in said conveying direction from the pair of press rolls to the delamination roll.

18. (Original) The pressure bonding apparatus of an orally administrable edible agent of laminate film form according to claim 17, characterized in that said delamination roll is rotatably disposed so as to rotate with movement of said one resin film.

19. (Currently Amended) The pressure bonding apparatus of an orally administrable edible agent of laminate film form according to claim 17-~~or~~ 18, characterized in that said winding shaft is disposed in a position where said one resin film only is drawn at an angle of 45° or more to the conveying direction of said other resin film with said delamination roll as a starting point.

20. (Original) The pressure bonding apparatus of an orally administrable edible agent of laminate film form according to claim 17, characterized in that said apparatus further comprises:

a pair of unwinding rolls that respectively feed said two resin films each provided with the orally administrable edible agent layer having the predetermined thickness on the surface thereof to said pair of press rolls; and

a winding roll that winds up, with said one resin film being delaminated by said delamination roll, said other resin film retaining the plural orally administrable edible agent layers conveyed by said conveyance mechanism, and

said unwinding roll and said winding roll have substantially the same dimension and structure and are interchangeable.

21. (Original) The pressure bonding apparatus of an orally administrable edible agent of laminate film form according to claim 17, characterized in that said apparatus further comprises:



a slitteer that cuts, with said one resin film being delaminated by said delamination roll, said other resin film retaining the plural orally administrable edible agent layers conveyed by said conveyance mechanism into narrow strips in parallel with the conveying direction; and

a plurality of winding reels each of which individually winds up each of the narrow strips obtained by cutting the other resin film retaining the plural orally administrable edible agent layers into a plurality of pieces by the slitteer,  
and

said plurality of winding reels are arranged so that their winding shaft portions except their flange portions are staggered backward and forward without gaps.

22. (Original) The pressure bonding apparatus of an orally administrable edible agent of laminate film form according to claim 17, characterized in that said apparatus further comprises:

a slitteer that can switch between an ON state where said one resin film is delaminated by said delamination roll, and said other resin film retaining the plural orally administrable edible agent layers conveyed by said conveyance mechanism is cut into narrow strips in parallel with the conveying direction, and an OFF state where said other resin film is passed through without being cut;

a shaft that supports a plurality of winding reels each of which individually winds up each of the narrow strips obtained by cutting the other resin film retaining the plural orally administrable edible agent layers into a plurality of pieces by the slitteer in the ON state; and

a winding roll that winds up said other resin film retaining the plural orally administrable edible agent layers conveyed by said conveyance mechanism through said slitteer in the OFF state without being cut, and

said shaft that supports the plurality of winding reels and said winding roll are interchangeable.

23. (Currently Amended) The pressure bonding apparatus of an orally administrable edible agent of laminate film form according to claim 21-~~or~~ 22, characterized in that said shaft that supports the plurality of winding reels is supported at both ends thereof by frames, one end of

said shaft can be supported so as to be cantilevered by one of said frames, and the other frame that supports the other end of said cantilevered shaft can be brought down and stood up.

24. (Currently Amended) The pressure bonding apparatus of an orally administrable edible agent of laminate film form according to claim 21~~-or-22~~, characterized in that each of said winding reels is rotatably supported by said shaft, side walls of each winding reel are pressed by a spring disposed at one end of said shaft and biased toward the other end of said shaft, and an biasing force of the spring causes rotation of the shaft to be transmitted to the winding reels.

25. (New) The method for producing an orally administrable edible agent of laminate film form according to claim 2, characterized in that one resin film to be delaminated in said resin film delaminating step is previously subjected to release treatment at least on a surface provided with the orally administrable edible agent layers.

26. (New) The method for producing an orally administrable edible agent of laminate film form according to claim 4, characterized in that one resin film to be delaminated in said resin film delaminating step is previously subjected to release treatment on both a front surface provided with the orally administrable edible agent layers and an opposite back surface, and the other resin film retaining the orally administrable edible agent layers without being delaminated in said resin film delaminating step is previously subjected to release treatment at least on a back surface provided with no orally administrable edible agent layer.

27. (New) The method for producing an orally administrable edible agent of laminate film form according to claim 2, characterized in that a pressure is 0.05 to 1.5 MPa when the resin films are joined so that said orally administrable edible agent layer surfaces face each other and are pressurized at the back surfaces.

28. (New) The method for producing an orally administrable edible agent of laminate film form according to claim 3, characterized in that a pressure is 0.05 to 1.5 MPa when the resin

films are joined so that said orally administrable edible agent layer surfaces face each other and are pressurized at the back surfaces.

29. (New) The method for producing an orally administrable edible agent of laminate film form according to claim 4, characterized in that a pressure is 0.05 to 1.5 MPa when the resin films are joined so that said orally administrable edible agent layer surfaces face each other and are pressurized at the back surfaces.

30. (New) The method for producing an orally administrable edible agent of laminate film form according to claim 2, characterized in that a temperature of the orally administrable edible agent layer is 50°C to 180°C when the resin films are joined so that said orally administrable edible agent layer surfaces face each other and are pressurized at the back surfaces.

31. (New) The method for producing an orally administrable edible agent of laminate film form according to claim 3, characterized in that a temperature of the orally administrable edible agent layer is 50°C to 180°C when the resin films are joined so that said orally administrable edible agent layer surfaces face each other and are pressurized at the back surfaces.

32. (New) The method for producing an orally administrable edible agent of laminate film form according to claim 4, characterized in that a temperature of the orally administrable edible agent layer is 50°C to 180°C when the resin films are joined so that said orally administrable edible agent layer surfaces face each other and are pressurized at the back surfaces.

33. (New) The method for producing an orally administrable edible agent of laminate film form according to claim 2, characterized in that a thickness of each of the orally administrable edible agent layers formed by pressure bonding said orally administrable edible agent layers is 1 to 300  $\mu\text{m}$ .

34. (New) The method for producing an orally administrable edible agent of laminate film form according to claim 3, characterized in that a thickness of each of the orally administrable

edible agent layers formed by pressure bonding said orally administrable edible agent layers is 1 to 300  $\mu\text{m}$ .

35. (New) The method for producing an orally administrable edible agent of laminate film form according to claim 4, characterized in that a thickness of each of the orally administrable edible agent layers formed by pressure bonding said orally administrable edible agent layers is 1 to 300  $\mu\text{m}$ .

36. (New) The method for producing an orally administrable edible agent of laminate film form according to claim 2, characterized in that said bonded orally administrable edible agent layers are self-supporting laminated films.

37. (New) The method for producing an orally administrable edible agent of laminate film form according to claim 3, characterized in that said bonded orally administrable edible agent layers are self-supporting laminated films.

38. (New) The method for producing an orally administrable edible agent of laminate film form according to claim 4, characterized in that said bonded orally administrable edible agent layers are self-supporting laminated films.